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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			FRENEL, VANEL	
			ART UNIT	PAPER NUMBER
			3626	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,193

Applicant(s)

RIFF ET AL.

Examiner

Vanel Frenel

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21,32-47 and 66-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21,32-47 and 66-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Request filed on 05/29/04. Claims 1-21, 32-47 and 66-74 are pending.
2. The finality mailed 10/20/04 is hereby withdrawn and Applicant's argument has been persuasive. Therefore, a new Office Action is forth coming.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-21, 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maus et al (6,602,469) in view of Cofano et al (2002/0059587)

(A) As per claim 1, Maus discloses an internet-based method for a paid service to maintain data connectivity of a remote medical device-configured patient to a database network and to enable medical device data exchange and processing (Col.7, lines 62-67 to Col.8, line 39), comprising the steps of : receiving in a substantially continuous manner at a database network site first data inputs uniquely representative of sensed physiologic information from a specific medical device configuration of a patient using said medical device configuration (Col.7, lines 62-67 to Col.8, line 39), enabling the

database network site to communicate with at least one web enabled web-site and to receive web-site originated signals requesting access to representations of said first data inputs from said database (Col.14, lines 20-67).

Maus does not explicitly disclose monitoring data packages to determine revenue for the service.

However, this feature is known in the art, as evidenced by Cofano. In particular, Cofano suggests monitoring data packages to determine revenue for the service (Page 2, Paragraph 0021).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Cofano within the system of Maus with the motivation of calculating service usage by user, service type, and outcomes; and providing calculated service usage to an administrator (Page 2, Paragraph 0021).

(B) As per claim 2, Cofano discloses the service method further including the step of providing said web-site and configuring said web-site with a user interface which includes a sign-in input to enable access to said database network site (Page 4, Paragraphs 0057-0059).

(C) As per claim 3, Maus discloses the service method in which the receiving step includes receiving at least one signal carrying information representing sensed physiologic status within the patient from at least one medical device located on or at least partially in the patient's body (Col.2, lines 46-67).

(D) As per claim 4, Maus discloses the service method in which the receiving step includes receiving signals carrying information representing actual physiologic phenomenon within the patient as sensed by at least one medical device located on or at least partially in the patient's body (Col.2, lines 46-67).

(E) As per claim 5, Maus discloses the service method in which the receiving step includes receiving signals carrying information representing actual physiologic phenomenon within the patient as sensed by a plurality of medical devices located on or at least partially in the patient's body (Col.11, lines 20-65).

(F) As per claim 6, Maus discloses the service method in which the enabling step comprises providing a secure sign-in and validating an originator's security-related action prior to allowing access of the originator to the database information (Col.23, lines 66-67 to Col.24, line 22).

(G) As per claim 7, Maus discloses the service method in which the first data inputs provides intermediate information to enable further production of data representations enabling subsequent actions (Col.25, lines 15-26).

(H) As per claim 8, Maus discloses an internet-based method for a paid service to maintain connection of a remote medical device configured patient to a database

network and for medical device data exchange and processing (Col.7, lines 62-67 to Col.8, line 39), comprising the steps of providing a web-site in a web-enabled system, the web-site having a user interface which includes a sign-in input to enable access to a database network site associated with said web-enabled system (Col.14, lines 20-67), receiving in a substantially continuous manner at the database network site first data inputs uniquely representative of sensed physiologic information from a device configuration of a patient using said medical device specific medical configuration (Col.7, lines 62-67 to Col.8, line 39), receiving at the web-site second data inputs requesting access to representations of said first data inputs available at said database (Col.14, lines 20-67).

Maus does not explicitly disclose enabling the originator of said second data inputs to have access to the database via the secure web site to view representations of said first data inputs.

However, this feature is well known in the art, as evidenced by Cofano. In particular, Cofano suggests enabling the originator of said second data inputs to have access to the database via the secure web site to view representations of said first data inputs (Page 9, Paragraphs 0092-0094).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Cofano within the system of Maus with the motivation of calculating service usage by user, service type, and outcomes; and providing calculated service usage to an administrator (Page 2, Paragraph 0021).

(I) Claims 9-13 recite the underlying process steps of the elements of claims 3-7, by or obvious in view of the collective teachings of Maus and Cofano, it is readily apparent that the apparatus disclosed by the applied prior art performs the recited underlying functions. As such, the limitations recited in claims 9-13 are rejected for the same reasons given above for method claims 3-7, and incorporated herein.

(J) As per claim 14, Maus discloses an internet-based method for a paid service to maintain enable medical device data exchange and processing (Col.7, lines 62-67 to Col.8, line 39), comprising the steps of receiving in a substantially continuous manner at a database network site data inputs uniquely representative of sensed physiologic information from a specific medical device configuration of a patient using said medical device configuration (Col.7, lines 62-67 to Col.8, line 39) initiating processing of said first data inputs to produce user accessible signals which represent the first data inputs in a user accessible format to enable action based on observations of the user accessible signals (Col.14, lines 20-67).

Maus does not explicitly disclose enabling the database network site to communicate with at least one web enabled web-site and to receive web-site originated signals requesting access to representations of said first data inputs from said database.

However, this feature is known in the art as evidenced by Cofano. In particular, Cofano suggests enabling the database network site to communicate with at least one web enabled web- site and to receive web-site originated signals requesting access to

representations of said first data inputs from said database (Page 9, Paragraphs 0092-0094).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Cofano within the system of Maus with the motivation of calculating service usage by user, service type, and outcomes; and providing calculated service usage to an administrator (Page 2, Paragraph 0021).

(K) As per claim 15, Cofano discloses the service method in which the step of initiating processing includes initiating analysis of the first data inputs to determine whether any sensed physiologic activity is abnormal (Page 7, Paragraphs 0081-0082; Page 8; Paragraph 0087).

(L) As per claim 16, Maus discloses the service method in which the step of initiating processing includes initiating analysis of the first data inputs to determine actual values for any sensed physiologic activity (Col.11, lines 20-65).

(M) As per claim 17, Maus discloses the service method in which the step of initiating processing includes initiating analysis of the first data inputs to determine whether any sensed physiologic activity is indicative of a demonstrable or likely pattern of physiological activity (Col.11, lines 20-65).

(N) As per claim 18, Maus discloses an internet-based method for a paid service to maintain data connectivity of a remote medical device-configured patient to a database network and to enable rapid medical device data exchange and processing of certain conditions (Col.7, lines 62-67 to Col.8, line 39), comprising the steps of receiving in a substantially continuous manner at a database network site first data inputs uniquely representative of sensed physiologic information from a specific medical device configuration of a patient using said medical device configuration (Col.7, lines 62-67 to Col.8, line 39).

Maus does not explicitly disclose enabling the database network site to communicate with at least one web-enabled web-site to automatically deliver representations of said first data inputs from said database when certain conditions are met.

However, this feature is known in the art, as evidenced by Cofano. In particular, Cofano suggests enabling the database network site to communicate with at least one web-enabled web- site to automatically deliver representations of said first data inputs from said database when certain conditions are met (Page 9, Paragraphs 0092-0094).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Cofano within the system of Maus with the motivation of calculating service usage by user, service type, and outcomes; and providing calculated service usage to an administrator (Page 2, Paragraph 0021).

(O) As per claim 19, Maus discloses the service method in which the step of enabling

includes initiating automatic software analysis of the first data inputs to determine whether any sensed physiologic activity is abnormal (Col.11, lines 20-65).

(P) As per claim 20, Maus discloses the service method in which the step of enabling includes initiating automatic software analysis of the first data inputs to determine actual values for any sensed physiologic activity (Col.11, lines 20-65).

(Q) As per claim 21, Maus discloses the service method in which the step of enabling includes initiating automatic software analysis of the first data inputs to determine whether any sensed physiologic activity is indicative of a demonstrable or likely pattern of physiological activity (Col.11, lines 20-65).

(R) As per claim 32, Maus discloses a computer- implemented method for improved data management in the healthcare industry by increasing patient engagement with recommended healthcare delivery modalities (Col.14, lines 20-67), comprising the steps of; b. configuring a patient accessible electronic interface to receive signals representative of sensed high relevance biological data of the patient (Col.11; lines 1-50), c. providing selectively programmable computer implemented rapid interpretations of the sensed high relevance biologic data and, when indicated, electronically sharing with the healthcare professional the details of the sensed high relevance biological data without resort to personal contact or face to face meeting between the healthcare professional and the patient (Col.141-65), and d. providing information flow paths for the

healthcare professional to further contribute to the knowledge database and patient engagement by offering the patient and a patient's designated advocate direct information about the high relevance biologic data thereby actively engaging the patient in a highly content rich yet efficient manner (Col.11, lines 1-50).

Maus does not explicitly disclose providing an implanted medical device configured for automatic sensing of high relevance biologic data of the patient and transmitting that data, or portions thereof to an information parser of the healthcare professional.

However, this known in the art, as evidenced by Cofano. In particular, Cofano suggests an implanted medical device which stimulating body organs and tissue to evoke a response for enhancing a body function or to control pain, and drug delivery devices for releasing a drug bolus at a selected site (Fig.10, Page 10; Paragraphs 0101-0104).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Cofano within the system of Maus with the motivation of calculating service usage by user, service type, and outcomes (Page 2, Paragraph 0021); and providing calculated service usage to an administrator (Page 2, Paragraph 0021).

(S) As per claim 33, Maus discloses a computer implemented internet-based method for an improved connect and monitoring service to rapidly connect remote persons to a database network for medical device data exchange and analysis (Col.7, lines 62-67 to

Col.8, line 39) said method being characterized in that it comprises the steps of providing a web-site having a user interface wherein the user interface includes a secure sign-in input to access a database network site (Col.6, lines 14-67), receiving at the web-site automatic inputs associated with a specific medical device and user of the device (Col.5, lines 51-65), and enabling the user to access the database via the web-site to use the service for real time monitoring of high relevance physiologic data mined from all monitored data of the user (Col.7, lines 62-67 to Col.8, line 39).

Maus does not explicitly disclose automatically confirming the identity of the medical device and the user.

However, this feature is known in the m, as evidenced by Cofano. In particular, Cofano suggests automatically confirming the identity of the medical device and the user (See Cofano, Page 5, Paragraphs 0065-0066).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Cofano within the system of Maus with the motivation of calculating service usage by user, service type, and outcomes; and providing calculated service usage to an administrator (Page 2, Paragraph 0021).

(T) As per claim 34, Maus discloses the method wherein said web-site further includes a proxy right access scheme to provide privileged access to a user's data by friends or family as programmed (Col.12, lines 54-65).

(U) As per claim 35, Maus discloses a computer implemented internet-based method for improved user compliance within a medical patient management system in which the system automatically determines which connection protocols to follow to rapidly connect one or more remote persons to a database network for medical device data exchange and analysis under certain conditions (Col.7, lines 62-67 to Col.8, line 39), said method being characterized in that it comprises the steps of providing a web-site having a user interface wherein the user interface includes a secure sign-in input protocol to access a database network site (Col.6, lines 14-67), receiving at the web-site automatic inputs associated with a specific medical device and user of the device, and performing computer implemented analyses to determine which user groups to rapidly and selectively automatically access the database via the web-site for receipt of high relevance physiologic data mined from all monitored data of the user (Col. (Col.7, lines 62-67 to Col.8, line 39).

Maus does not explicitly disclose automatically confirming the identity of the medical device and the user.

However, this feature is known in the art, as evidenced by Cofano. In particular, Cofano suggests automatically confirming the identity of the medical device and the user (See Cofano, Page 5, Paragraphs 0065-0066).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Cofano within the system of Maus with the motivation of calculating service usage by user, service type, and outcomes; and providing calculated service usage to an administrator (Page 2, Paragraph 0021).

(V) As per claim 36, Maus discloses the computer implemented internet-based method for improved user compliance further comprising: alerting a select group of medical providers to an event using an event service (Col.6, lines 14-67), enabling the select group of medical providers to execute secure access to the device user's database in a single sign-on action per user in the group (Col.8, lines 25-67 to Col.9, line 16).

(W) As per claim 37, Maus discloses the method wherein said single sign-on action includes authentication to a foreign web-site that is passed over to access the secure device user's database (Col.6, lines 14-67).

(X) As per claim 38, Maus discloses the method further characterized by computer implemented automatic formatting of automatically processed high relevance data mined from all detected data and electronically pushing the formatted data to an electronic display of at least one member of a group of medical providers whereby at least one of the group of medical providers selectively provides commentary and then directs a data transmission back via the web site to the user of the medical device, to a designated advocate of the user of the medical device, and, optionally, to another member of a medical providers group (Col.15, lines 13-39).

(Y) As per claim 39, Maus discloses a computer implemented patient management network configured for implementing the method of automatically determining which connection protocols to follow to rapidly connect one or more remote persons to a database network for medical device data exchange and analysis under certain conditions, said network being characterized in that it comprises: a web site having a user interface wherein the user interface includes a secure sign-in input protocol to access a database network site (Col.6, lines 14-67), sensing and signal components for providing automatic inputs to the web site associated with a specific medical device and user of the device (Col.7, lines 62-67 to Col.8, line 39).

Maus does not explicitly disclose processing routines and module for automatically confirming the identity of the medical device and the user; and processing routines and module for performing computer implemented analyses to determine which user groups to rapidly and selectively automatically access the database via the web-site for receipt of high relevance physiologic data mined from all monitored data of the user.

However, these features are known in the art, as evidenced by Cofano. In particular, Cofano suggests processing routines and module for automatically confirming the identity of the medical device and the user (See Cofano, Page 5, Paragraphs 0065-0066); and processing routines and module for performing computer implemented analyses to determine which user groups to rapidly and selectively automatically access the database via the web-site for receipt of high relevance

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physiologic data mined from all monitored data of the user (See Cofano, Page 5, Paragraphs 0065-0066).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Cofano within the system of Maus with the motivation of calculating service usage by user, service type, and outcomes; and providing calculated service usage to an administrator (Page 2, Paragraph 0021).

5. Claims 40-47 and 66-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maus et al (6,602,469) in view of Cofano et al (2002/0059587) as applied to claims 1-21, 32-47 above and further in view of Kumar et al (6,416,471).

(AA) As per claim 40, Maus discloses a server hosting medical and physiological data collected from the patient, a physician station in data communications with the server (Col.25, lines 62-67 to Col.26, line 42), and a health care system information network being in a bi-directional communication with the physician station and further having a data communication with the server (Col.25, lines 62-67 to Col.26, line 42), a disease management organization in bi-directional communications with said health care system information network (Col.13, lines 12-67; Col.14, lines 51-67 to Col.15, line 39); said server including at least one set of database of information concerning the patient wherein the database is structured to assist the disease management organization to manage the patient for a fee (See Cofano, Page 2, Paragraph 0021); said server including means enabling the database to communicate with at least one web-enabled

web-site and to receive web-site originated signals requesting access to the database (See Cofano, Page 9, Paragraphs 0092-0094).

Maus and Cofano do not explicitly disclose a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices.

However, this feature is known in the art, as evidenced by Kumar. In particular, Kumar suggests a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices (See Kumar, Col.61-67 to Col.8, line 60).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(BB) As per claim 41, Maus discloses a server hosting medical and physiological data collected from the patient, a physician station in data communications with the server, and a health care system information network being in a bi-directional communication

with the physician station and further having a data communication with the server (Col.25, lines 62-67 to Col.26, line 42), a disease management organization in bi-directional communications with said health care system information network (Col.13, lines 12-67; Col.14, lines 51-67 to Col.15, line 39); said server including at least one set of database of information concerning the patient wherein the database is structured to assist the health care system information network to manage the patient or a fee (See Cofano, Page 2, Paragraph 0021); said server including means enabling the database to communicate with at least one web-enabled web-site and to receive web-site originated signals requesting access to the database (See Cofano, Page 9, Paragraphs 0092-0094).

Maus and Cofano do not explicitly disclose a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices.

However, this feature is known in the art, as evidenced by Kumar. In particular, Kumar suggests a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices (See Kumar, Col.61-67 to Col.8, line 60).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(CC) As per claim 42, Maus discloses a server hosting medical and physiological data collected from the patient, a physician station in data communications with the server (Col.25, lines 62-67 to Col.26, line 42); a health care system information network being in a bi-directional communication with the physician station and further having a data communication with the server (Col.25, lines 62-67 to Col.26, line 42); a healthcare system information network being in a bi-directional communication with the physician station and further having a data communication with the server (Col.13, lines 12-67; Col.14, lines 51-67 to Col.15, line 39); said server including at least one set of database of information concerning the patient wherein the database is structured to assist the health care system information network to manage the patient or a fee (See Cofano, Page 2, Paragraph 0021); said server including means enabling the database to communicate with at least one web-enabled web-site and to receive web-site originated signals requesting access to the database (See Cofano, Page 9, Paragraphs 0092-0094).

Maus and Cofano do not explicitly disclose a system for implementing a disease management service for a remote chronic patient with an implantable medical device

and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices.

However, this feature is known in the art, as evidenced by Kumar. In particular, Kumar suggests a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices (See Kumar, Col.61-67 to Col.8, line 60).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(DD) As per claim 43, Maus discloses a server hosting medical and physiological data collected from the patient (Col.25, lines 62-67 to Col.26, line 42); a physician station in data communications with the server (Col.25, lines 62-67 to Col.26, line 52); and a disease management organization in bi-directional communications with said server and said physician station (Col.15, lines 1-39); said server including at least one set of database of information concerning the patient wherein the database is structured to assist the health care system information network to manage the patient or a fee (See

Cofano, Page 2, Paragraph 0021); said server including means enabling the database to communicate with at least one web-enabled web-site and to receive web-site originated signals requesting access to the database (See Cofano, Page 9, Paragraphs 0092-0094).

Maus and Cofano do not explicitly disclose a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices.

However, this feature is known in the art, as evidenced by Kumar. In particular, Kumar suggests a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices (See Kumar, Col.61-67 to Col.8, line 60).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

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(EE) As per claim 44, Maus discloses a server hosting high relevance medical and physiological data accessible via a remote monitor in data communications with the server (Col.25, lines 62-67 to Col.26, line 42), the server being web-enabled to host and provide multi-directional data collections from various services including said person so that the collected data may be re-transmitted for a fee provided by one or more recipients of the data (See Cofano, Page 2, Paragraph 0021); said server including means enabling the database to communicate with at least one web-enabled web-site and to receive web-site originated signals requesting access to the database (See Cofano, Page 9, Paragraphs 0092-0094).

Maus and Cefano do not explicitly disclose a data collection and transfer system for implementing a chronic remote patient monitoring service for transmission of very high relevance medical and physiological data from a person having at least one implanted and/or wearable medical device; and at least one medical device implanted or wearably located on a person being in data communication with the remote monitor.

However, these features are known in the art, as evidenced by Kumar. In particular, Kumar suggests a data collection and transfer system for implementing a chronic remote patient monitoring service for transmission of very high relevance medical and physiological data from a person having at least one implanted and/or wearable medical device (See Kumar, Col.61-67 to Col.8, line 60); and at least one medical device implanted or wearably located on a person being in data communication with the remote monitor (See Kumar, Col.61-67 to Col.8, line 60).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(FF) As per claim 45, Kumar discloses the service wherein said at least one implanted and/or wearable medical device is in wireless communication with the remote monitor to enable data communications when the person is ambulatory (See Kumar, Fig.1; Col.8, lines 4-60).

(GG) As per claim 46, Cofano discloses the service wherein said server includes programmable parameters to bill the person for services rendered (See Cofano, Page 2, Paragraph 0021).

(HH) As per claim 47, Maus discloses a server hosting medical and physiological data collected from a patient at a remote location, said server being in data communications with a remote monitor that collects highly relevant data from the patient (Col.25, lines 62-67 to Col.26, line 42), a physician station (Col.14, lines 51-67); a health care system information network in data communications with the server and the physician station (Col.8, lines 25-67); a billing service for the remote management of the patient's health (See Cefano, Page 2, Paragraph 0021).

Maus and Cefano do not explicitly disclose a system for implementing a computerized healthcare information service network capable of collecting medical data from various remote locations including a patient with a medical device; having at least one implanted and/or externally worn medical device; and a service of the performance of at least one implanted and/or externally worn medical device communicating with the physician station for expert opinion and advising the patient in real time, to provide as to proper procedures to follow for therapy and medical care.

However, these features are known in the art, as evidenced by Kumar. In particular, Kumar suggests a system for implementing a computerized healthcare information service network capable of collecting medical data from various remote locations including a patient with a medical device (See Kumar, Col.8, lines 4-60); having at least one implanted and/or externally worn medical device (See Kumar, Col.8, lines 4-60); and a service of the performance of at least one implanted and/or externally worn medical device communicating with the physician station for expert opinion and advising the patient in real time, to provide as to proper procedures to follow for therapy and medical care (See Kumar, Col.38, lines 1-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(II) As per claim 66, Maus discloses a network-enabled system for implementing a chronic data management and monitoring service for remote patients and medical devices (Col.25, lines 62-67 to Col.26, line 42), comprising: a server computer hosting high relevance data transmitted from the remote patients and medical devices (Col.25, lines 62-67 to Col.26, line 42), a client computer providing access to a plurality of users of the service (Col.25, lines 1-61); and wherein said server computer provides a user interface whereby said plurality of users are authenticated prior to accessing said data (Col.25, lines 1-61).

Maus and Cefano do not explicitly disclose whereby the service is available via one of a secure Internet channels to enable an authenticated user to access data pertaining to a specific patient and/or medical device.

However, this feature is known in the art as evidenced by Kumar. In particular, Kumar suggests whereby the service is available via one of a secure Internet channels to enable an authenticated user to access data pertaining to a specific patient and/or medical device (See Kumar, Col.38, lines 1-40).

(JJ) As per claim 67, Maus discloses the service wherein said service utilizes billing and collection systems consisting of one of computer to computer transactions, monthly statements, direct credit card transfer, micro-payment-systems and business to business collection systems (Col.7, lines 45-67).

(KK) As per claim 68, Maus discloses an internet-based information network service for

implementing medical data transfer and exchange in a health care system (Col.14, lines 51-67), means enabling the database network site to communicate with at least one web-enabled web-site and to receive web-site originated signals requesting access to the database (See Cofano, Page 9, Paragraphs 0092-0094).

Maus and Cefano do not explicitly disclose means for collecting medical data from multiple remote sites, and interface means for accessing said means for collecting by authorized agents; wherein said interface means includes controls for authenticating a user for the service and provides selection criteria and display at any one of said multiple remote sites for the user.

However, these features are known in the art as evidenced by Kumar. In particular, Kumar suggests means for collecting medical data from multiple remote sites, and interface means for accessing said means for collecting by authorized agents (See Kumar, Col.14, lines 10-67); wherein said interface means includes controls for authenticating a user for the service and provides selection criteria and display at any one of said multiple remote sites for the user (See Kumar, Col.15, lines 40-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(LL) As per claim 69, Maus discloses the information system comprising: a server hosting data transmitted from a remote patient (Col.25, lines 62-67 to Col.26, line 42), a plurality of client computers providing access to the server (Col.25, lines 62-67 to Col.26, line 42); a medical device manufacturer computer being in data communications with the server wherein device data is managed to provide at least one functional group within a medical device manufacturer with highly relevant information derived from the medical device performance data for use in product or service improvement actions (See Cofano, Page 4, Paragraphs 0056-0059).

Maus and Cofano do not explicitly disclose an information system for generating medical device performance data, in real time, to enhance product performance and adapt businesses methods to provide a continuously improving service to a chronic patient or other information users.

However, this feature is known in the art, as evidenced by Kumar. In particular, Kumar suggests an information system for generating medical device performance data, in real time, to enhance product performance and adapt businesses methods to provide a continuously improving service to a chronic patient or other information users (See Kumar, Col.1, lines 22-68).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(MM) As per claim 70, Cofano discloses system in which the functional sub-group is one of research and development, product planning, post market surveillance, and sales and marketing (Cofano, Page 6, Paragraph 0071).

(NN) As per claim 71, Cofano discloses the system in which the other information users include one of disease management organizations and healthcare management organizations (Cofano, Page 1, Paragraphs 0003-0004).

(OO) As per claim 72, Maus discloses a system for implementing networked remote patient management services comprising: a server hosting high relevance patient management data (Col.25, lines 62-67 to Col.26, line 42), said server being accessible via client computers wherein said client computers include a web-enabled system, said server being accessible via client computers wherein said client computers include a web-enabled system, a medical device manufacturer web-site, a physician site, a health care information network site, and a disease management organization (See Cofano, Page 9, Paragraphs 0092-0094); each of said client computers being in data communications with the server to import specific data on which the patient management services billing schemes, for at least one service, are implemented (See Cefano, Page 2, Paragraph 0021).

Muas and Cofano do not explicitly disclose for providing chronic monitoring of the remote patients with chronic disease having implantable medical devices and/or wearable devices (See Kumar, Col.61-67 to Col.8, line 60).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(PP) As per claim 73, Maus discloses an internet-based method in a web-enabled system for a paid service to connect a remote patient to a database network for medical device data exchange and processing (Col.14, lines 36-67) comprising the steps of providing a web-site in a web-enabled system, the web-site having a user interface which includes a secure sign-in input to access a database network site associated with said web-enabled system (See Cofano, Page 9, Paragraphs 0092-0094), automatically receiving at the database network site first data inputs uniquely associated with a specific medical device and patient using said medical device (See Maus Col.8, lines 25-67; Col.11, lines 20-65); receiving at the web-site second data inputs requesting access to representations of said first data inputs (See Cefano, Page 4, Paragraphs 0057-0059); enabling the originator of said second data inputs to have access to the database to view representations of said first data inputs (See Cefano, Page 4, Paragraphs 0057-0059);

Maus and Cefano do not explicitly disclose confirming the identity of the medical device, the patient, and the originator of said second data inputs.

However, this feature is known in the art, as evidenced by Kumar. In particular, Kumar suggests confirming the identity of the medical device, the patient, and the originator of said second data inputs (See Kumar, Col.14, lines 24-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

(QQ) As per claim 74, Maus discloses an internet-based method in a web-enabled system for a paid service to connect a remote patient to a database network for medical device data exchange and processing (Col.14, lines 36-67) comprising the steps of providing a web-site in a web-enabled system, the web-site having a user interface which includes a secure sign-in input to enable access to a database network site associated with said web-enabled system (See Cofano, Page 9, Paragraphs 0092-0094), periodically receiving at the database network site first data inputs uniquely associated with a specific medical device and patient using said medical device (See Maus Col.8, lines 25-67; Col.11, lines 20-65); receiving at the web-site second data inputs requesting access to representations of said first data inputs (See Cefano, Page 4, Paragraphs 0057-0059), enabling the originator of said second data inputs to have

access to the database via the secure web site to view representations of said first data inputs (See Cefano, Page 4, Paragraphs 0057-0059).

Maus and Cefano do not explicitly disclose confirming the identity of the medical device, the patient, and the obligator of said second data inputs.

However, this feature is known in the art, as evidenced by Kumar. In particular, Kumar suggests confirming the identity of the medical device, the patient, and the originator of said second data inputs (See Kumar, Col.14, lines 24-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Kumar within the collective teachings of Maus and Cofano with the motivation of providing remote monitoring systems which permit a doctor or nurse to monitor the conditions of several hospitalized patients from a central monitoring site in the hospital (See Kumar, Col.1, lines 64-66).

Response to Arguments

6. Applicant's arguments on 05/29/04 with respect to claims 1-21, 32-39, 40-47 and 66-74 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches method and system for remotely monitoring multiple medical parameters in an integrated medical monitoring system (6,364,834), system and method for managing patient care (US 2002/0169636) and real time ambulatory patient monitor (5,544,661).

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on Monday-Thursday from 6:30 am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are 703- 305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

V.F
V.F

January 18, 2005



ALEXANDER KALINOWSKI
PRIMARY EXAMINER